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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,838	07/31/2003	Giulio Tarro	A32408-PCT-USA-A (072900.	3630
21003	7590	01/12/2006	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			SANG, HONG	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/631,838		TARRO, GIULIO	
	<b>Examiner</b>		<b>Art Unit</b>	
	Hong Sang		1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-4 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

**RE: Tarro**

1. The numbering of claims 24-27 in the application filed on 7/31/03 is incorrect.

Claims have been re-numbered under 37 CFR 1.126 as claims 1-4.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to in part to a method of increasing the expression of a protein comprising SEQ ID NO.1 in non-small cell lung cancer cells of a mammal comprising administering to said mammal cisplatin, classified in class 424, subclass 600, for example.
- II. Claim 1, drawn to in part to a method of increasing the expression of a protein comprising SEQ ID NO.1 in non-small cell lung cancer cells of a mammal comprising administering to said mammal etoposide, classified in class 424, subclass 236.1.
- III. Claim 2, drawn to in part to a method of increasing the expression of a protein comprising SEQ ID NO.2 in non-small cell lung cancer cells of a mammal comprising administering to said mammal cisplatin, classified in class 424, subclass 600, for example.
- IV. Claim 2, drawn to in part to a method of increasing the expression of a protein comprising SEQ ID NO.2 in non-small cell lung cancer cells of a

mammal comprising administering to said mammal etoposide, classified in class 424, subclass 236.1.

- V. Claim 3, drawn to in part to a method of increasing the expression of a protein comprising SEQ ID NO.3 in non-small cell lung cancer cells of a mammal comprising administering to said mammal cisplatin, classified in class 424, subclass 600, for example.
- VI. Claim 3, drawn to in part to a method of increasing the expression of a protein comprising SEQ ID NO.3 in non-small cell lung cancer cells of a mammal comprising administering to said mammal etoposide, classified in class 424, subclass 236.1.
- VII. Claim 4, drawn to in part to a method of increasing the expression of a protein comprising SEQ ID NO.4 in urogenital cancer cells of a mammal comprising administering to said mammal cisplatin, classified in class 424, subclass 600, for example.
- VIII. Claim 1, drawn to in part to a method of increasing the expression of a protein comprising SEQ ID NO.4 in urogenital cancer cells of a mammal comprising administering to said mammal etoposide, classified in class 424, subclass 236.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

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The instant specification does not disclose that these methods would be used together.

Groups I-VIII are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation.

Each invention performs this function using a structurally and functionally divergent material and comprises different methodological steps. For group I, cisplatin is used, and the expression of protein comprising SEQ ID NO. 1 in non-small cell lung cancer cells is measured, for group II, etoposide is used, and the expression of protein comprising SEQ ID NO. 1 in non-small cell lung cancer cells is measured, for group III, cisplatin is used, and the expression of protein comprising SEQ ID NO. 2 in non-small cell lung cancer cells is measured, for group IV, etoposide is used, and the expression of protein comprising SEQ ID NO. 2 in non-small cell lung cancer cells is measured, for group V, cisplatin is used, and the expression of protein comprising SEQ ID NO. 3 in non-small cell lung cancer cells is measured, for group VI, etoposide is used, and the expression of protein comprising SEQ ID NO. 3 in non-small cell lung cancer cells is measured, for group VII, cisplatin is used, and the expression of protein comprising SEQ ID NO. 4 in urogenital cancer cells is measured, for group VIII, etoposide is used, and the expression of protein comprising SEQ ID NO. 4 in urogenital cancer cells is measured. SEQ ID NO. 1-4 are structurally and functionally distinct. Non-small cell lung cancer and urogenital cancer are distinct because their distinct etiology and property. Different genes and/or proteins are overexpressed in different cancers. Different methods are used for diagnosing and treating different cancers. Moreover,

while cisplatin and etoposide are both chemotherapeutic agents, they are structurally and functionally distinct. Therefore, the methods of Groups I-VIII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. Searching groups I-VIII are not coextensive. Separate sequence searches are required for different groups. As such, it would be burdensome to search the inventions of Groups I-VIII together.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

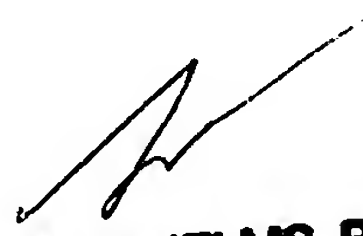
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

LARRY R. HELMS, PH.  
SUPERVISORY PATENT EX

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang  
Art Unit 1643  
Jan. 6, 2005



**LARRY R. HELMS, PH.D.**  
**SUPERVISORY PATENT EXAMINER**